

REMARKS

Entry of the foregoing and reexamination and reconsideration of the above-captioned application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112 are respectfully requested. All of the previously presented claims 1-28 are presented again as amended, except claims 4 and 29, which has been canceled. New claim 30 has been added.

Turning to the rejection, applicant acknowledges the withdrawal of the objection to the drawings, the acknowledgement of the cancellation of claims 6 and 7, the withdrawal of the rejection of claim 19 pursuant to 35 U.S.C. § 112, second paragraph, the withdrawal of the rejection of claim 1 and the claims dependant therefrom as being anticipated by Grushka et al., U.S. Patent No. 5,660,701 ("Grushka"), and the reconsideration and withdrawal of the rejections over Lauer et al. in view of Alter et al. Applicant does not necessarily agree with the examiner's reasons for those withdrawals. However, their withdrawal has been acknowledged.

Claim 4 has been objected to pursuant to 37 C.F.R. § 1.75(c) as allegedly being an improper dependant claim for failing to further limit the subject matter of the previous claims. Claim 4 has been canceled, although it should be noted that the phrase "blood proteins" found therein was an incorrect translation of the French PCT application, which included the term "protéines sériques" which clearly translates to "serum proteins." Corrections to the specification where appropriate have been made to reflect this.

Claims 1, 18, 26 and 28 were objected to for a number of informalities. The undersigned thanks the examiner for pointing these out and all have been corrected.

Claim 27 was rejected pursuant to 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Applicant respectfully traverses. A

review of the English language specification at page 4 specifically recites, in the third line from the bottom, mixtures of the recited biological buffers. Therefore, there is express written description support for the claim recitation. Withdrawal of the rejection is therefore respectfully requested.

Claim 28 has been rejected pursuant to 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Applicant respectfully disagrees that this claim is not clear and definite. Claim 26 requires serum, plasma, urine and cerebral spinal fluids. Claim 28 is making it clear that the materials of interest within those biological fluids are constituent proteins. Applicant submits that the claim, particularly when read in light of the specification, is clear and definite and therefore, no amendment should be required. Notwithstanding, applicant would like to thank the examiner for the suggestion for a way of amending claim 28, which in no way modifies its scope. Accordingly, applicant has availed itself to the examiner's suggestion and amended claim 28 accordingly.

Claims 26 and 28 were rejected pursuant to 35 U.S.C. § 102(b) as allegedly being anticipated by Grushka. Applicant respectfully disagrees. However, the recitations of claim 29 have been added to claim 26, specifically reciting that the buffering material not be an amino acid. Grushka teaches only the use of amino acids and therefore it cannot anticipate nor render obvious the claimed invention.

Claims 1, 3, 4, 6, 8-11, 17 and 22-29 are rejected to 35 U.S.C. § 103(a) as allegedly being unpatentable over Keo et al., U.S. Patent No. 5,599,433 ("Keo"). To the extent that those rejections would be applied to the claims as amended, applicant respectfully traverses. First, the Patent Office takes the position that the clinical specimens taught in Keo inherently contain the recited proteins claimed. Certainly the clinical specimens in human biological fluids could contain such

proteins, but it is not inherent that they will. Human biological fluids could be deficient in these materials for one or a number of reasons, both natural and artificial. Inherency, a concept which is typically not used in an obviousness context, requires that something necessarily and always occurs, and there is no evidence of record that that is the case. Accordingly, the Patent Office's position, based on the evidence of record, cannot support such a rejection.

Note that Keo only teaches separation of hemoglobin-based blood protein not the proteins recited in accordance with the present invention, which are found in, for example, serum. Of course, they can be isolated and separated and analyzed from other sources as amply demonstrated in claim 3. Nonetheless, techniques used for identifying, determining and separating serum proteins such as albumin and globulins are clearly not the same as those designed for separation of hemoglobin and one of ordinary skill in the art would not assume that a particular buffer system or process methodology useful for one would also be useful for the other. Moreover, it is well-known that proteins can be very different from one another in terms of their physical and chemical properties such as molecular weight, isoelectric properties and structure. The electrophoretic separation of proteins is based, in no small part, on how the separation is performed and how the proteins interact with the buffering compositions. Therefore, even if physicochemical properties of proteins are similar, which applicant does not concede is the case here, the effect of a buffer, for example, would be expected to be totally different. Thus, one could not and would not accept the teachings of Keo as being in any way applicable to the separation of the types of serum proteins described in the independent claims.

Moreover, the processes according to Keo and that of the present invention are different. In Keo, the goal is to detect

the presence of certain proteins -- not those described in the instant application. The technique described is very specific and tailored to detecting that material. To suggest that it would therefore be possible to detect the proteins in accordance with the present invention using that technique as taught in Keo requires a huge leap of faith, one which is clearly not supported by the evidence of record.

Even if good results are obtained for specific constituents such as Hb Alc in the case of Keo, nothing can be concluded for other portions of the analytical spectrum -- other protein constituents. See, for example, comparative example 11 of the instant specification, which uses a usual borate buffer and shows that the capillary electrophoresis methods are very sensitive with regard to some specific constituents.

It is also important to note that there is nothing in Keo to suggest the use of the particular buffers of the present invention in connection with separation of the materials described and claimed in the present invention and it is the method which is claimed here. There is no teaching, suggestion or motivation to use the specific buffer composition pieced together from Keo's disclosure to separate constituents specifically enumerated in accordance with the present invention rather than for detection of other constituents as taught by Keo.

Applicant also wishes to draw the examiner's attention to new claim 30, which includes all of the recitations of current claim 1, but also specifically identifies borate compounds that are used, none of which are specifically in Keo.

As claims 2, 12-16 and 18-21 were only rejected on formalities, and as these have been addressed, an indication that these claims are allowed, or at least would be if rewritten in independent form, is appropriate.


Applicant again acknowledges the provisional double patenting rejection but needs not comment as it is provisional.

Should the examiner have any questions with regard to the foregoing, it is respectfully requested that he/she telephone applicant's attorney, at the examiner's convenience, at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the examiner is authorized to charge Deposit Account No. 12-1095 therefor. From the foregoing, further and favorable action in the form of a notice of allowance is believed to be next in order and such action is earnestly solicited.

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Respectfully submitted,

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